IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KILEY WOLFE,	:	**CIVIL ACTION**
	:	
Plaintiff,	:	
	:	
v.	:	**NO. 07-348**
	:	
MCNEIL-PPC, INC.; MCNEIL CONSUMER & SPECIALTY PHARMACEUTICALS, a division of MCNEIL-PPC, INC.; MCNEIL CONSUMER HEALTHCARE, a division of MCNEIL-PPC, INC.; and JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC,	:	
	:	
Defendants.	:	

DuBOIS, J. **January 27, 2012**

M E M O R A N D U M

I. INTRODUCTION

In this products liability action, plaintiff Kiley Wolfe alleges that Children's Motrin manufactured and marketed by defendants caused her to develop Stevens-Johnson Syndrome ("SJS") and Vanishing Bile Duct Syndrome. Presently before the Court are defendants' renewed Daubert motions to exclude or limit the testimony of four of plaintiff's proposed expert witnesses.[1] For the reasons that follow, the Court denies one of defendants' motions. The three

[1]Defendants withdrew their original Daubert motions relating to these four proposed expert witnesses because they were unable to schedule the experts' depositions. See Wolfe v. McNeil-PPC Inc., No. 07-348 (E.D. Pa. Oct. 14, 2010) (order granting defendants' request to withdraw the motions). On September 22, 2011, the Court granted defendants leave to re-file the motions. See Wolfe v. McNeil-PPC Inc., No. 07-348 (E.D. Pa. Sept. 22, 2011). Because defendants still have not deposed the individuals at issue, the re-filed motions rely on their expert

remaining motions are granted in part and denied in part.

II. BACKGROUND

By Memorandum and Order of March 30, 2011, the Court denied defendants' motion for summary judgment as to plaintiff's failure-to-warn and punitive-damages claims. Wolfe v. McNeil-PPC, Inc., 773 F. Supp. 2d 561 (E.D. Pa. 2011). The Court granted the motion in all other respects. Id. The factual background of the case is set forth in detail in the Memorandum of March 30, 2011, and will not be repeated in this Memorandum except as is necessary to explain the Court's rulings.

III. LEGAL STANDARD—FEDERAL RULE OF EVIDENCE 702

Federal Rule of Evidence ("Rule") 702 provides as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

The "pathmarking" Supreme Court cases interpreting Rule 702 are Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993), and Kumho Tire v. Carmichael, 526 U.S. 137 (1999). United States v. Mitchell, 365 F.3d 215, 234 (3d Cir. 2004). In Daubert, the Supreme Court held that "[f]aced with a proffer of expert scientific testimony . . . the trial judge must determine at the outset . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." Daubert, 509 U.S. at 592. In Kumho

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reports in this case and depositions taken in other litigation.

Tire, the Supreme Court made clear that the Daubert gatekeeping function extends beyond scientific testimony to testimony based on "technical" and "other specialized" knowledge. 526 U.S. at 141.

Under Daubert, courts must address a "trilogy of restrictions" before admitting expert testimony: qualification, reliability, and fit. Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003); see also Elcock v. Kmart Corp., 233 F.3d 734, 741 (3d Cir. 2000). The party offering the expert must prove each of these requirements by a preponderance of the evidence. In re TMI Litig., 193 F.3d 613, 663 (3d Cir. 1999). Defendants challenge only the first two: qualification and reliability. Thus, the Court does not address the issue of fit.

A. Qualification

To qualify as an expert, "Rule 702 requires the witness to have 'specialized knowledge' regarding the area of testimony." Betterbox Commc'ns Ltd. v. BB Techs., Inc., 300 F.3d 325, 335 (3d Cir. 2002) (quoting Waldorf v. Shuta, 142 F.3d 601, 625 (3d Cir. 1998)). The Third Circuit has instructed courts to interpret the qualification requirement "liberally" and not to insist on a certain kind of degree or background when evaluating the qualifications of an expert. See Waldorf, 142 F.3d at 625. "The language of Rule 702 and the accompanying advisory committee notes make clear that various kinds of 'knowledge, skill, experience, training, or education,' qualify an expert as such." In re Paoli R.R. Yard PCB Litig., 916 F.2d 829, 855 (3d Cir. 1990) ("Paoli I") (quoting Fed. R. Evid. 702).

Moreover, "[t]his liberal policy of admissibility extends to the substantive as well as the formal qualifications of experts." Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008). Thus, "it is an abuse of discretion to exclude testimony simply because the trial court does not

deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." Id. (quoting Holbrook v. Lykes Bros. S.S. Co., 80 F.3d 777, 782 (3d Cir. 1996)).

B. Reliability

The reliability requirement of Daubert "means that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 (3d Cir. 1994) ("Paoli II") (quoting Daubert, 509 U.S. at 590). The Supreme Court held in Kumho Tire that the Daubert test of reliability is "flexible" and "the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination." 526 U.S. at 141-42 (emphasis omitted). In determining whether the reliability requirement is met, courts examine the following factors where appropriate:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

Mitchell, 365 F.3d at 235 (citing Paoli II, 35 F.3d at 742 n.8). These factors are neither exhaustive nor applicable in every case. Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 806-07 (3d Cir. 1997).

Under the Daubert reliability prong, parties "do not have to demonstrate to the judge by a

preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable." Paoli II, 35 F.3d at 744 (emphasis omitted). "The evidentiary requirement of reliability is lower than the merits standard of correctness." Id. "As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." Mitchell, 365 F.3d at 244 (quoting Ruiz-Troche v. Pepsi Cola of P.R. Bottling Co., 161 F.3d 77, 85 (1st Cir. 1998)).

IV. DEFENDANTS' DAUBERT MOTIONS

The Court addresses each of defendants' renewed Daubert motions in turn.

A. Motion to Exclude Testimony Related to Dr. Manuela Neuman's "Lymphocyte Toxicity Assay"

In their first renewed Daubert motion, defendants seek to limit the causation testimony of Dr. Manuela Neuman. Dr. Neuman is an Assistant Professor of Pharmacology and Toxicology at the University of Toronto. She is also the CEO and director of a private firm called In Vitro Drug Safety and Biotechnology. Plaintiff proposes to have Dr. Neuman testify, based in part on her Lymphocyte Toxicity Assay ("LTA") analysis of plaintiff's blood, that ibuprofen, the active ingredient in Children's Motrin, caused plaintiff's SJS.

A simplified explanation of the LTA methodology is as follows[2]: Dr. Neuman injected ibuprofen into a sample of plaintiff's blood and observed the amount of cell death that resulted.

[2]Dr. Neuman's expert report provides a more technical explanation. (See Neuman Report ¶¶ 37-68.)

(Neuman Report ¶¶ 74, 77.) She observed significantly more cell death than normal. (Id. ¶ 78.) According to Dr. Neuman, when considered along with plaintiff's medical records and the temporal link between her use of ibuprofen and development of SJS, this result "confirms that ibuprofen was the incriminating drug." (Id.)

1. The Parties' Arguments

Defendants contend that Dr. Neuman's LTA methodology is unreliable, both as a general matter and as applied in this case. They do not challenge Dr. Neuman's qualifications or the "fit" of her testimony to the present case. The Court finds defendants' reliability arguments unpersuasive.

Defendants argue first that Dr. Neuman's method of LTA analysis is not reliable as a general matter. Dr. Neuman did not invent LTA analysis, but she modified other researchers' procedures. Defendants assert that Dr. Neuman's method is not generally accepted in her field because she cites only a few hospitals that have used it. Moreover, according to defendants, it is not an outgrowth of a reliable methodology, because Dr. Neuman states that other researchers' LTA procedures, from which hers evolved, are more "subjective" and rely heavily on the researchers' visual perception of the results. Defendants further argue that evidence of the LTA analysis should be excluded because Dr. Neuman has not specified how much ibuprofen she injects into blood samples, and thus her methodology cannot be replicated.

Second, defendants argue that plaintiff has not proven that the LTA analysis was applied reliably in this case. They assert that the only data Dr. Neuman has provided is the "Toxicity %" she found in plaintiff's blood, which is essentially the conclusion of the analysis. She has not disclosed the amount of ibuprofen she used or the results of tests on other blood samples.

Defendants argue that this would make it impossible to cross-examine Dr. Neuman at trial.

Plaintiff responds by citing medical treatises that support the use of LTA analysis. She also points out that defendants have deposed Dr. Neuman in other cases and cross-examined her during a 2008 trial in California state court.

2. Analysis

Dr. Neuman's LTA analysis has several strong indicia of reliability. The Court thus denies defendants' motion. Defendants can address any weaknesses in her testimony on cross-examination and through competing expert testimony.

First, Dr. Neuman has published at least two peer-reviewed journal articles and three abstracts concerning her method of LTA analysis. She first developed her LTA methodology in "a controlled trial that was published in a peer-reviewed scientific journal that was never done for the purposes of litigation." (Neuman Report ¶ 26.)

Second, contrary to defendants' contention, Dr. Neuman's technique is an outgrowth of a well-established methodology. Dr. Neuman describes the change she made to the conventional method of LTA analysis as relatively minor. (See id. ¶ 66.) Moreover, Dr. Neuman cites "a litany of scientific literature [from] the last [twenty] years . . . which support[s] the use of the LTA . . . for many different drugs." (Id. ¶ 25.) Many treatises and other publications discuss LTA analysis as a tool to determine the causation of drug-associated illnesses. That the interpretation of LTA results ordinarily requires some subjective judgment does not render the technique unreliable.

Third, the Third Circuit has held that "the qualifications of the expert witness testifying based on [a] methodology" are relevant to the reliability of that methodology. United States v.

Mitchell, 365 F.3d 215, 235 (3d Cir. 2004). Dr. Neuman's qualifications are impressive. She holds a doctorate, is a professor at a major research institution, and is licensed by multiple organizations in many different countries. She has served as the director of various laboratories at hospitals around the world and has lectured extensively about her LTA technique and related topics.

Fourth, the accuracy of Dr. Neuman's and others' methods of LTA analysis has been tested. Dr. Neuman cites several journal articles stating that the specificity and sensitivity of the LTA—indicators of its predictive value—exceed ninety percent for ibuprofen and other drugs. (Neuman Report ¶ 62.) She observed an eighty-nine percent correlation between the results of her LTA tests and patients' clinical diagnoses. (Id. ¶ 63.) Her expert report documents her use of controls in developing and applying the test, (id. ¶¶ 64, 66), and the procedure by which she "validate[d] the ibuprofen LTA" (id. ¶¶ 57-61).

Finally, Dr. Neuman's failure to detail the amount of ibuprofen used and some other aspects of her methodology does not render that methodology unreliable. Dr. Neuman's expert report provides a thorough description of the procedure she followed. (See id. ¶¶ 57-61, 65-67, 74-79.) Defendants do not cite any authority for the proposition that an expert's report must provide enough information that the opposing party can replicate her analysis. They may cross-examine Dr. Neuman regarding the amount of ibuprofen she used.

B. Motions to Exclude Testimony of Robert C. Nelson, Ph.D.; Roger Salisbury, M.D.; and Randall Tackett, Ph.D.[3]

In their other three motions, defendants seek to limit the testimony of Drs. Robert C.

[3]Because these three motions raise largely the same legal issues, the Court addresses them together.

Nelson, Roger Salisbury, and Randall Tackett. Plaintiff proposes having Drs. Nelson, Salisbury, and Tackett discuss McNeil's compliance with FDA regulations—including the adequacy of McNeil's labeling and disclosure of safety information—and causation. Dr. Tackett's proposed testimony also covers an alleged design defect in Children's Motrin. Defendants make various challenges to the three experts' qualifications and the reliability of their opinions. The Court grants in part and denies in part defendants' motions to exclude the testimony of Drs. Nelson, Salisbury, and Tackett.

Dr. Nelson is an epidemiologist and clinical pharmacist by training. He worked at the FDA for over twenty years, where he focused on new drug review, epidemiology, and post-marketing surveillance. He is now the president of a drug-safety consulting firm and an adjunct professor at the University of Maryland's School of Pharmacy.

Dr. Salisbury is a plastic surgeon specializing in burn and hand surgery. He has treated over four hundred patients for SJS and related disorders. He is a Professor of Plastic Surgery and Chief of Plastic and Reconstructive Surgery at New York Medical College, as well as Director of the Burn Center and Chief of Plastic Surgery at Westchester Medical Center. He was the lead author of a 2005 Citizen's Petition that warned the FDA of the link between ibuprofen and SJS and persuaded the FDA to strengthen requirements for the ibuprofen warning label.

Dr. Tackett is a Professor of Pharmacology and Toxicology at the University of Georgia. He teaches graduate students about drug regulation and has made presentations to FDA employees about drug safety and relevant FDA regulations. He coauthored the 2005 Citizen's Petition.

The Court analyzes the three motions as follows: First, the Court addresses defendants'

qualification arguments. Defendants argue that (1) none of the three proposed experts are qualified to testify regarding FDA regulation and (2) Drs. Salisbury and Tackett are not qualified to testify regarding causation. Second, the Court discusses defendants' challenges to the reliability of (1) all three proposed experts' regulatory testimony, (2) all three proposed experts' causation testimony, and (3) Dr. Tackett's design-defect testimony. Finally, the Court analyzes issues regarding state-of-mind testimony and legal conclusions.

1. Qualification to Testify Regarding FDA Regulation

Defendants assert that Drs. Nelson, Salisbury, and Tackett are not qualified to testify regarding defendants' compliance with applicable FDA regulations. Defendants contend that Dr. Nelson is not qualified because his responsibilities at the FDA centered on drug safety, not drug labeling or regulatory compliance. They assert that Dr. Salisbury "is not a regulatory expert," has never drafted labeling, and did not review the federal labeling regulations before being retained in litigation. (Defs.' Mot. Exclude Salisbury 5-8.) They further argue that Dr. Tackett is not qualified because he has never worked for the FDA, reviewed a New Drug Application, or drafted a label for an over-the-counter drug. These arguments are rejected.

"[I]t is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified or because the proposed expert does not have the specialization that the court considers most appropriate." Kannakeril v. Terminix Int'l, Inc., 128 F.3d 802, 809 (3d Cir. 1997) (citation omitted). Under this liberal standard, Drs. Nelson, Salisbury, and Tackett are qualified to testify regarding defendants' compliance with applicable FDA regulations.

Dr. Nelson worked for the FDA for twenty years, where he focused primarily on drug

safety. He also, among other things, trained FDA staff on "regulatory science" and related matters. (Nelson Report 2.) His post-FDA experience has provided him with additional experience in regulatory affairs. Dr. Nelson is thus qualified to testify regarding FDA regulation and McNeil's regulatory compliance. See Lofton v. McNeil Consumer & Specialty Pharm., No. 3:05-1531, 2008 WL 4878066, at *9 (N.D. Tex. July 25, 2008) (holding Dr. Nelson qualified to opine regarding drug labeling); see also Robinson v. McNeil Consumer Healthcare, No. 07-5603 (N.D. Ill. Aug. 12, 2009) (order denying a Daubert motion that made the same arguments with respect to Dr. Nelson's qualifications).

While Dr. Salisbury may present a closer case, he is likewise qualified. As lead author of the 2005 Citizen's Petition, Dr. Salisbury engaged extensively with the relevant FDA regulations. Moreover, in his academic capacity, he instructs his students "how to review labels for prescription and OTC medications so that they can appropriately communicate warnings to their patients." Lofton, 2008 WL 4878066, at *9; see also Bartlett v. Mutual Pharm. Co., Inc., 742 F. Supp. 2d 182, 199 (D.N.H. 2010) (holding Dr. Salisbury qualified to testify regarding "drug labeling and FDA regulatory procedures").

Dr. Tackett is similarly qualified to testify regarding FDA regulation. He is an experienced pharmacologist and toxicologist and has taught graduate students and FDA employees about FDA regulations. As a research investigator for drug companies, Dr. Tackett studied federal regulations regarding "drug development and labeling." (Pl.'s Answer Opp'n Defs.' Mot. Exclude Tackett 9.) He also gained experience with FDA regulation in connection with the 2005 Citizen's Petition. "[Dr. Tackett's] 'extensive experience' is enough to qualify him as an expert in this area." Bartlett, 742 F. Supp. 2d at 198; see also Lofton, 2008 WL

4878066, at *9.

2. Qualification to Testify Regarding Causation

Defendants argue that Drs. Tackett and Salisbury are not qualified to testify regarding causation. That contention is also rejected.

Defendants assert that Dr. Tackett is not qualified to testify as to causation because he is a pharmacologist and toxicologist, not a medical doctor. However, the Third Circuit rejected an analogous argument in Paoli I, reversing a district court that excluded a toxicologist's causation testimony on those grounds. See 916 F.2d 829, 855 (3d Cir. 1990). The Third Circuit emphasized that the district court should not have held the expert unqualified "simply because [she] did not have the degree or training which the district court apparently thought would be most appropriate." Id.

Dr. Tackett holds a doctorate in Pharmacology and Toxicology and has been a professor for thirty years. He is familiar with relevant medical and scientific literature, clinical data, and epidemiological studies. (Tackett Report ¶ 4.) He has also, for example, taught students about the "mechanisms of actions and side effects of [non-steroidal anti-inflammatory drugs]," including SJS. (Id. ¶ 5.) This experience qualifies him to present causation testimony, notwithstanding his lack of a medical degree. See Lofton, 2008 WL 4878066, at *8-9.

With respect to Dr. Salisbury, defendants argue that "to the extent [he] bases his opinion on his interpretation and analysis of epidemiological studies, he is unqualified to do so" because he "is not an epidemiologist." (Defs.' Mot. Exclude Salisbury 14.) For the same reasons stated with respect to Dr. Tackett, the Court rejects this argument. See Paoli I, 916 F.2d at 855. Even if Dr. Salisbury does not have the particular degree or training that might be "most appropriate" to

interpret epidemiological literature, his extensive medical training and experience are sufficient.[4]

3. Reliability of Testimony Regarding Failure to Comply with FDA Regulations

Plaintiff proposes to have Drs. Nelson, Salisbury, and Tackett testify that defendants withheld information regarding SJS occurrences from the FDA and failed to conduct a proper safety analysis of ibuprofen. Dr. Nelson's proposed testimony includes his opinion that the warning label for Children's Motrin was inadequate. Defendants assert that the three experts' regulatory testimony is unreliable because it lacks factual support and that such testimony would not assist the jury.[5] The Court rejects these arguments.

All three experts' reports provide ample factual support for their contentions. They include detailed tables documenting the accumulation of knowledge of the link between non-steroidal anti-inflammatory drugs and SJS. Dr. Nelson reviewed McNeil's safety database and identified adverse reactions that did not appear in the scientific literature or in data McNeil reported to the FDA. Based on this analysis, plaintiff argues that McNeil withheld evidence of the reactions. Similarly, Drs. Salisbury and Tackett reviewed the New Drug Applications and quarterly and annual reports McNeil submitted to the FDA and concluded that McNeil failed to

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[4]Defendants also argue that, because Dr. Salisbury is not a liver specialist, he is not qualified to testify regarding the general or specific causation of plaintiff's alleged Vanishing Bile Duct Syndrome ("VBDS"). This narrow question has not been fully briefed. Plaintiff does not respond to the argument and, although Dr. Salisbury's expert report mentions VBDS in passing, the report focuses almost exclusively on SJS and toxic epidermal necrolysis, a related disorder. The Court's rulings in this Memorandum and Order are without prejudice to aggrieved parties' right to seek reconsideration, so if Dr. Salisbury is questioned regarding VBDS at trial, defendants may object and renew their argument that he is not qualified to testify on that issue.

[5]Defendants also mention in passing that Federal Rule of Evidence 403 compels the exclusion of Dr. Salisbury's opinion that McNeil withheld SJS information from the FDA. However, defendants do not offer any argument to support this assertion.

include relevant information regarding the link between ibuprofen and SJS.

Moreover, contrary to defendants' assertion, Dr. Nelson's opinion that the Children's Motrin label was inadequate is reliable. Dr. Nelson cites factual bases for the opinion, including the FDA's response to the 2005 Citizen's Petition. The opinion is not "based on his belief as to what the FDA implicitly thinks about Children's Motrin when it requires label changes." (Defs.' Mot. Exclude Nelson 9.) Defendants are correct that Dr. Nelson may not opine regarding the FDA's state of mind, but his expert report does not do so. Cf. Lofton, 2008 WL 4878066, at *9 (permitting Dr. Nelson to testify regarding the adequacy of the Motrin label, although focusing on his qualification to present such testimony).

Finally, the Court rejects defendants' argument that the three doctors' testimony on regulatory issues will not assist the trier of fact. "Under Rule 702, an expert can be employed if his testimony will be helpful to the trier of fact in understanding evidence that is simply difficult, though not beyond ordinary understanding." United States v. Downing, 753 F.2d 1224, 1229 (3d Cir. 1985) (internal quotations and alterations omitted). Many of the regulation-related documents in this case are complicated and confusing to a person lacking a background in science or medicine. Expert testimony will help the jury comprehend those documents and will highlight the important aspects of the data, such as what McNeil was obligated to report to the FDA. If the testimony veers into areas that are no longer helpful to the jury, defendants may object at trial.

4. Reliability of General Causation Testimony

Defendants argue that the three proposed experts' opinions that ibuprofen can cause SJS are unreliable because they rely in part on case reports. Defendants further contend that Dr.

Nelson's general causation opinion is unreliable because he endorses a 2003 study ("SCAR") while "disregarding" a related 2008 study ("EuroSCAR"). These assertions lack merit.

The Court rejected an analogous case-report argument in its May 4, 2011, Daubert opinion in this litigation. See Wolfe v. McNeil-PPC, Inc., No. 07-348, 2011 WL 1673805, at *5 (E.D. Pa. May 4, 2011). Like the experts addressed in that opinion, Drs. Nelson, Salisbury, and Tackett "did not solely rely on case reports in forming their opinions on causation but used them to supplement their extensive review of plaintiff's medical records" and other evidence, including epidemiological studies and other peer-reviewed literature. Id. "[T]he three doctors' use of case studies in reaching their conclusion affects only the weight to be given their testimony, not its admissibility." Id.

Furthermore, Dr. Nelson explains at length why he favors the SCAR study over the EuroSCAR study. (Nelson Report 35-40.) In his report, he recognizes the relevance of EuroSCAR but explains that he has concerns regarding its methodology. (See id.) As the district court stated in Lofton, the differences between the SCAR and EuroSCAR studies "raise a fact issue with respect to general causation, and the parties will have the ability to question their experts as to the differences between the two studies." Lofton v. McNeil Consumer & Specialty Pharm., 682 F. Supp. 2d 662, 672-73 (N.D. Tex. 2010). Defendants may cross-examine Dr. Nelson about his criticism of the EuroSCAR study, but it is not grounds for precluding his testimony.

5. Reliability of Dr. Tackett's Design-Defect Theory

Defendants also seek to preclude Dr. Tackett from opining that "dexibuprofen is a safer alternative to ibuprofen." (Defs.' Mot. Exclude Tackett 12-13.) Defendants assert that "neither

the science nor the facts" support an opinion that dexibuprofen is safe or practical. (Id. at 14.) They buttress this assertion primarily with the report of one of their own experts.

The Court rejects this argument. The Court's role is not to determine "whether the proffered evidence is actually correct" but merely to determine whether the expert has "good grounds" for his opinion. 4 Weinstein's Federal Evidence § 702.05[3] (2d ed. 2011); see also Paoli II, 35 F.3d at 744 ("The evidentiary requirement of reliability is lower than the merits standard of correctness."). Under this standard, Dr. Tackett's design-defect opinion is admissible. See Lofton, 2008 WL 4878066, at *6 ("Dr. Tackett's design [defect] theory . . . meets the Daubert requirements of relevance and reliability.").

Dr. Tackett details the basis for his opinion that dexibuprofen is a feasible and safer alternative to ibuprofen, and he supports his argument with citations to dozens of scholarly articles. (Tackett Report 54-59.) Defendants offer only the conclusions of their own expert, which they argue prove Dr. Tackett is wrong. However, this conflict on the merits does not render Dr. Tackett's opinion unreliable. See, e.g., Fed. R. Evid. 702 committee notes ("When a trial court . . . rules that an expert's testimony is reliable, this does not necessarily mean that contradictory expert testimony is unreliable. The amendment is broad enough to permit testimony that is the product of competing principles or methods in the same field of expertise.").

6. Admissibility of Testimony Regarding Legal Conclusions and the State of Mind of Defendants and the FDA

Finally, defendants seek to exclude Drs. Salisbury and Tackett's opinions regarding the state of mind of defendants and the FDA and expressing legal conclusions. For example, Dr. Salisbury's expert report states that "a company like McNeil is willing to risk the lives of

innocent Americans on a confidence interval." (Salisbury Report ¶ 50.) He also refers to defendants' conduct as "negligent" and "reckless." Dr. Tackett's report makes similar statements. (See Pl.'s Answer Opp'n Mot. Exclude Tackett 14 ("By indicating that McNeil did not act in a 'reasonable and prudent' manner, Dr. Tackett is simply stating that McNeil was negligent.").) Both doctors also opined in their reports regarding the FDA's likely reaction had defendants fully disclosed their product's risks. (See id. ¶¶ 52, 53, 78.)

The Court rules that expert testimony regarding the state of mind of defendants and the FDA, and expert testimony that constitutes a legal opinion, is inadmissible.[6] "[I]ntent is not a proper subject for expert testimony." Robinson v. Hartzell Propeller, Inc., 326 F. Supp. 2d 631, 648 (E.D. Pa. 2004); see also In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) (excluding expert testimony regarding "the intent, motives or states of mind of corporations, regulatory agencies and others"). Likewise, "[a]lthough Federal Rule of Evidence 704 permits an expert witness to give expert testimony that embraces an ultimate issue to be decided by the trier of fact, an expert witness is prohibited from rendering a legal opinion." Berckley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 217 (3d Cir. 2006). Thus, as the Court ruled in its May 4, 2011, Daubert opinion in this case, "to the extent [an expert] plans to testify that [a defendant] behaved negligently in the conduct of its business, such testimony constitutes an

[6]Defendants do not challenge Dr. Nelson's testimony on these grounds. However, Dr. Nelson's expert report contains conclusions about defendants' culpability. (See, e.g., Nelson Report 4 ("It is my opinion that McNeil was negligent for failing to adequately provide or disclose all safety information to the FDA . . . . ").) Dr. Nelson's expert report also states that an inadequate warning label rendered Children's Motrin "unreasonably dangerous," (id.), which constitutes an inadmissible legal conclusion, see, e.g., Strong v. E.I. DuPont de Nemours Co., 667 F.2d 682, 685-86 (8th Cir. 1981). Like his colleagues, Dr. Nelson may not present such testimony at trial.

improper legal opinion. . . . It will be the role of the jury, not [the expert], to determine if [the defendant] acted negligently." Wolfe, 2011 WL 1673805, at *8.

Drs. Nelson, Salisbury, and Tackett will not be permitted to testify at trial with respect to the state of mind of defendants or the FDA. Likewise, they are prohibited from expressing legal conclusions by stating such things as "defendants' conduct was negligent" or that an inadequate warning label rendered Children's Motrin "unreasonably dangerous."

V. CONCLUSION

For the foregoing reasons, the Court denies defendants' motion to exclude the testimony of Dr. Neuman. The Court grants in part and denies in part defendants' motions to exclude the testimony of Drs. Nelson, Salisbury, and Tackett. The rulings in this Memorandum are without prejudice to the rights of the aggrieved parties to (1) seek reconsideration at or before trial, if warranted by the evidence, or (2) object at trial to improper questions of, and inadmissible evidence offered by or through, any expert. An appropriate Order follows.